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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,936	03/10/2004	Martial G. Bourassa	5233-103 US	3284

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	
MAIL DATE	**DELIVERY MODE**
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,936	BOURASSA ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed **9/24/07** presents remarks and arguments to the office action mailed **3/24/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by www.lifeclinic.com March 2001, 5 pages.

The reference teaches with regard to instant claim 1 administering an ACE inhibitor to patients with impairment of glucose in a non-diabetic population. See underling page 2, first paragraph. It is Examiners' understanding that the non-diabetic population is inclussive of said set populations such as chronic heart failure and

impaired fasting glucose, see page 1, last two lines and page 2 first line. Also the reference teaches administering rapipril to lower incidence of diabetes and significantly decrease incidence of cardiovascular event. See underling page 3.

Claims 1 and 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Norhammar et al. European Heart J. 2000, 21, 1293-1294.

The reference teaches administering an ACE inhibitor to patients with chronic heart failure and fasting plasma glucose wherein the chronic heart failure is symptomatic left ventricular systolic dysfunction as required by instant claims 1, 3 and 4. The reference teaches ACE inhibitors will inhibit the development of diabetes. See underling throughout entire document. It is Examiners' understanding that administering the ACE inhibitor will inherently reduce the onset of diabetes.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Bicket, Clinical Pharmacology, 2002 66(3) 461-468.

Bicket teaches administering ACE inhibitors to non-diabetic patients. Note that non-diabetic patients population is inclussive of CHF and impairment FPG population. See page 467. The reference further teaches the patient populations are with asymptomatic left ventricular dysfunction. See underlining page 461 as required by instant claim 3. The reference further teaches with regard to instant claims 5-7 the ACE inhibitor is enalapril administered in a dosage of 5-20 mg. See pages 462 and 464 underlining.

Old Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 3-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Vermes et al. Circulation 2003;107;1291-1296 Feb. 17 (submitted by Applicant).

Withdrawn based on Declaration 131 and is persuasive.

Claims 1, 5 and 6, 23 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yusuf et al. JAMA 2001;286(15);1882-1885 (submitted by Applicant). Claim 23 has been added to the rejection. As evidence by Previtt http:/yourtotalhealth.ivillage

Applicant argues that the reference fails to teach subjects with chronic heart failure.

In response, this is found unpersuasive because the reference see page 1882, wherein administering of ramipril (ACE inhibitor) reduces myocardial infaction and or coronary artery disease among patients without diagnosis of diabetes. Coronary atery disease is a chronic disease in which the coronary arteries gradually hardens and narrow is a condition referred to as coronary heart disease as evidence by Previtt. See enclose reference Previtt underlining section, page 6. Also, it is understood by having the population of patients without diagnosis of diabetes is inclussive of patients with chronic heart failure and impaired fasting plasma glucose.

Applicant's arguments have been fully considered but they are not persuasive. See above reasons and the rejection is repeated below.

The above reference teaches ACE inhibitor ramipril reduces myocardial infarction such as strokes, death in the development of nephropathy-(see page 1882 first col. and mid sec of 2nd col.) thus diabetic nephropathy is kidney disease that develops as a result of diabetes mellitus (DM) and chronic heart failure (myocardial infarction) occurs when an area of heart muscle dies or is permanently damaged because of an inadequate supply of oxygen to that area as in the instant claims 1, and 5, wherein the ace inhibitor is is administered in a dosage of 10 mg per day (see page 1883 line 10) as in claim 6. With regard to claim 23 see Table 1, beta-blocker is concurrently being giving with an ACE inhibitor ramipril.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Heart J. 2000, 21, 1293-1294 and Bicket, Clinical Pharmacology, 2002 66(3) 461-468 in view of Yusuf et al. JAMA 2001;286(15);1882-1885 and Knight et al. Amer. Heart J. 138(5, part 1):849-855 taken with Bauters et al. Cardiovascular Diabetology , 2003, 2:1 pages 1-16

European Heart J., Bicket and Yosuf et al. are applied here as above.

The above reference teaches with regards to the instant claim 1, administering ACE inhibitors to patients in order to reduce renal function in patients, diabetes is associated with an increased risk of renal impairment in patients with chronic heart failure, but the risk was reduced when an ACE inhibitor enalpril was administered as in claims 1, 5 and 7 (see conclusion-highlighted). (Diabetes is a generic term for the different types of diabetes-therefor diabetes mellitus is inclussive).

The Bauters et al. reference teaches the said chronic failure (CHF) is a result of left ventricular systolic dysfunction (see page 5, lft.col first para. highlighted sec) as in claims 3 and 4, wherein the subject has impaired fasting plasma glucose (see page 5, lft.col 2nd para. highlighted sec) as in claim 2, wherein the drug is an ACE inhibitor – enalapril as in claims 1 and 7.

One of ordinary skill in the art would have been motivated to combine the above cited art administer enalapril an ACE inhibitor to inhibit the incidence of diabetes mellitus in a subject with chronic heart failure because the prior art teaches so and has

been shown that diabetes mellitus is prevalent in heart failures as taught by Bauters et al. (see abstract) and one would have been motivated to administer the drug in the range of 5 mg-20 mg per day.

The motivation comes from the teachings of the cited prior art above. Ace inhibitors are administered to patients to reduce renal function in patients with an increased risk of CHF.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
11/30/07

12/9/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER